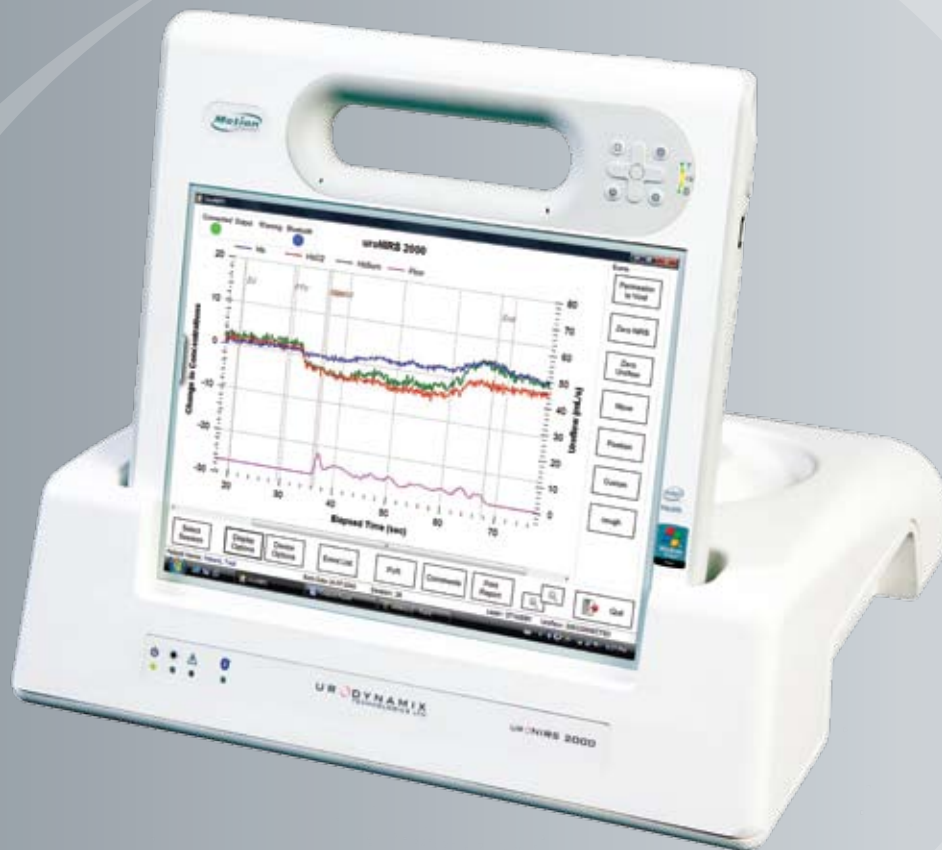


uroNIRS2000™

Bladder Monitor System



*Innovative solution
for bladder monitoring*

Non-Invasive

- Eliminates catheters used in conventional urodynamics (UDS) and the associated complications, fear, and pain^{1,2,3}
- Suitable for patients unable to or who refuse to undergo conventional UDS
- Improves patient compliance

Accurate

- 86% sensitivity and 89% specificity for detecting BOO compared to conventional invasive UDS^{1, 4}
 - Avoids the error associated with catheterization in measuring flow rates (Qmax)⁵
- † *Used in conjunction with uroflowmeter and ultrasound devices*

Efficient

- Fast and easy catheter-free procedure (5-10 minutes)
- Compact and portable system for fast setup
- Cost effective - one operator and one disposable sensor patch

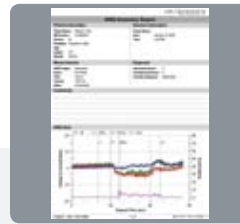
uroNIRS 2000™



- **Tablet PC**
Wireless Tablet PC running the uroNIRS software communicates with the base station via Bluetooth®
- **Base Station**
Generates near infrared (NIR) light, receives near infrared spectroscopy (NIRS) signal from the sensor, and processes data for diagnosis
- **Patch**
Single use, disposable patch connects to the optical sensor cable and is placed on the patient's abdomen just superior to the pubic bone
- **Calibration Analyzer**
An accessory used in regular testing of the sensor cable to ensure optimal performance of the uroNIRS 2000™ system
- **Optical Sensor Cable**
Optical cable with sensor to deliver NIR light to the bladder and detect the light reflected back from the bladder

Required Accessories:

- Uroflow meter: for measuring the maximum urinary flow rate (Qmax)
- Ultrasound: for measuring postvoid residual volume (PVR)
- Printer



INDICATIONS:

The uroNIRS 2000™ device is indicated for non-invasive testing of bladder activity in an office or hospital setting.

INTENDED USE:

The uroNIRS 2000™ device is intended to be used in conjunction with commercially available uroflowmeters and bladder ultrasound systems for non-invasive testing of bladder activity, aiding in the diagnosis of urinary incontinence and lower urinary tract symptoms. The device is used under the direction of a licensed physician or health care professional.

Key Technical Specifications (refer to the user manual for details):

uroNIRS 2000™ BASE STATION

Electrical Input: 100 – 240VAC, 50 – 60Hz, 85VA
 Dimensions: 275mm (L) x 340mm (W) x 100mm (H)
 Weight: 4.5 kg
 Wireless communication: Bluetooth® 2.0, Class 2
 Laser specifications: Maximum Output Power: 2.2MW, Class 1

TABLET PC

Operating Systems: Windows Vista® Business
 Display: 10.4" XGA TFT LCD (1024 x 768)
 Communication: Integrated Bluetooth®
 Embedded I/O: 13.56Mhz RFID reader
 Dimensions: 10.0" x 10.0" x .95" (256mm x 256mm x 24.3mm)
 Weight: 3.3 lbs. (1.50 kg) (with Lithium-ion battery)

OPTICAL SENSOR CABLE

Cable jacketing material: Silicon rubber (latex-free)
 Optical sensor material: Polyurethane elastomer (latex-free)
 Length: 4.5 m

SENSOR PATCH

Material: Thermoplastic elastomer compound (latex-free)
 Adhesive: Medical grade, pressure-sensitive acrylic (latex-free)

References:

- 1 Klingler HC, Madersbacher S, Djavan B, Schatzl G, Marberger M, Schmidbauer CP. Morbidity of the evaluation of the lower urinary tract with transurethral multichannel pressure-flow studies. *J Urol.* 1998 Jan; 159(1):191-4
- 2 Greenstein A, Bar-Yosef Y, Chen J, Matzkin H. Does information provided to men before a urodynamic study affect their expectation of pain? *BJU Int.* 2005 Dec; 96(9):1307-9
- 3 Choe JH, Lee JS, Seo JT. Urodynamic studies in women with stress urinary incontinence: Significant bacteriuria and risk factors. *Neurourol Urodyn.* 2007;26(6):847-51
- 4 Macnab AJ, Stothers L. Near-infrared Spectroscopy: Validation of bladder-outlet obstruction assessment using non-invasive parameters. *Can J Urol.* 2008; 15(5): 4241-4248
- 5 Issa MM, Chun T, Thwaites D, Bouet R, Hall J, Miller LE, Ritenour CW. The effect of urethral instrumentation on uroflowmetry. *BJU Int.* 2003 Sep; 92(4):426-8

Distributed by:

Manufactured by:

URODYNAMIX TECHNOLOGIES LTD.

Suite 1485 Bentall Centre Two
 555 Burrard St., Box 213
 Vancouver, BC, V7X 1M9
 +1 604 694-7770
 info@urodynamix.com www.urodynamix.com

